DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 19, 2014

Physio-Control, Inc.
Sylvia Lemke
Principal Regulatory Affairs Specialist
11811 Willows Road Northeast
P.O. Box 97006
Redmond, Washington 98052

Re: K142430
Trade/Device Name: Lifepak 15 Monitor/Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LDD, DRT, DRO, DQA, DXN, DSK, CCK, FLL, LDD
Dated: November 20, 2014
Received: November 21, 2014

Dear Sylvia Lemke,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION D: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K142430**

Device Name: **LIFEPAK 15 monitor/defibrillator**

Indications For Use:

Manual Defibrillation:

Indications
Manual defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

Contraindications
Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

Automated External Defibrillation:

Indications
AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 15 monitor/defibrillator is not intended for use on pediatric patients less than 8 years old.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION D: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K142430

Device Name: **LIFEPAK 15 monitor/defibrillator**

Indications For Use:

Noninvasive Pacing

Indications
Noninvasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

Contraindications
Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

12-lead Electrocardiography:

Indications
The 12-lead electrocardiogram is used to identify, diagnose and treat patients with cardiac disorders and is useful in the early detection and prompt treatment of patients with acute ST-elevation myocardial infarction (STEMI).

Pulse Oximetry

Indications
Pulse Oximetry is indicated for use in any patient who is at risk of developing hypoxemia, carboxyhemoglobinemia, or methemoglobinemia. SpO_2 monitoring may be used during no motion and motion conditions, and in patients who are well or poorly perfused. SpCO and SpMet accuracies have not been validated under motion or low perfusion conditions.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION D: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K142430

Device Name: **LIFEPAK 15 monitor/defibrillator**

Indications For Use:

Noninvasive Blood Pressure Monitoring:

Indications
Noninvasive blood pressure monitoring is intended for detection of hypertension or hypotension and monitoring BP trends in patient conditions such as, but not limited to, shock, acute dysrhythmia, or major fluid imbalance.

End-Tidal CO2 monitoring:

Indications
$EtCO_2$ monitoring is used to detect trends in the level of expired CO_2. It is used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully.

Invasive Pressure Monitoring:

Indications
Invasive pressure monitoring is indicated for use in patients who require continuous monitoring of physiological pressures in order to rapidly assess changes in the patient's condition or response to therapy. It may also be used to aid in medical diagnosis.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION D: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K142430

Device Name: **LIFEPAK 15 monitor/defibrillator**

Indications For Use:

Temperature Monitoring:

Indications
Temperature monitoring is indicated for use in patients who require continuous monitoring of body temperature.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION E: 510(K) SUMMARY

Submitter:

Physio-Control, Inc.
11811 Willows Road Northeast
P.O. Box 97006
Redmond, Washington 98073-9706

Contact Person:

Sylvia Lemke
Principal Regulatory Affairs Specialist
Phone: 425-867-4171, Fax: (425) 867-4154

Date Summary Prepared:

August 28, 2014

Device Trade Name:

LIFEPAK®15 monitor/defibrillator

Device Common Name:

External monitor/defibrillator

Device Classification:

Classification Name	Class	Product Code
Low Energy DC-Defibrillator (Including Paddles), (21CFR 870.5300)	II	LDD
Automatic External Defibrillators (Non-Wearable) (21CFR 870.5310)	III	MKJ
Cardiac Monitor (Including Cardiotachometer & Rate Alarm) (21CFR870.2300)	II	DRT
External Cardiac Transcutaneous (Non-Invasive) Pacemaker (21CFR870.5550)	II	DRO
Oximeter (21CFR870.2700)	II	DQA
Noninvasive Blood Pressure Measurement System (21CFR870.1130)	II	DXN
Carbon-Dioxide Gas Analyzer Gaseous-Phase (21CFR868.1400)	II	CCK
Blood Pressure Computer (21CFR870.1110)	II	DSK
Clinical Electronic Thermometer (21CFR880.2910)	II	FLL

SECTION E: 510(K) SUMMARY

Predicate Device:

The features and functions of the proposed LIFEPAK 15 monitor/defibrillator are substantially equivalent to the previously cleared LIFEPAK 15 monitor/defibrillator. The 510(k) clearance numbers for the predicate devices are below:

Predicate Device	510(k) Number	Clearance Date
LIFEPAK® 15 monitor/defibrillator	K082937	March 11, 2009
LIFEPAK® 15 monitor/defibrillator	K103567	March 22, 2011

Description:

The LIFEPAK 15 monitor/defibrillator is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols. The LIFEPAK 15 monitor/defibrillator was designed for use in a variety of hospital and pre-hospital settings including emergency rooms, catheterization laboratories, electrophysiology laboratories, crash carts, operating rooms, and ground ambulances.

Features of the LIFEPAK 15 monitor/defibrillator include manual and automated external defibrillation, noninvasive pacing, ECG monitoring (3-lead, 7-lead and interpretive 12-Lead), pulse oximetry (SpO_2, SpCO, and SpMet), synchronized cardioversion, noninvasive blood pressure monitoring, end-tidal CO_2 monitoring, invasive pressure monitoring, and temperature monitoring. The LIFEPAK 15 monitor/defibrillator is powered by rechargeable lithium-ion batteries or from AC power sources via an AC power adapter or DC power sources via a DC power adapter.

The primary difference between the proposed LIFEPAK 15 monitor/defibrillator and the previously cleared predicate device is a combination of software and hardware modifications completed to support component obsolescence. The proposed LIFEPAK 15 monitor/defibrillator includes the same monitoring features, defibrillation waveform, pacing waveform, and Shock Advisory System™ algorithm as the previously cleared predicate device. Additionally, there are no changes to the intended use or indications for use of the previously cleared predicate device.

Intended Use:

The LIFEPAK 15 monitor/defibrillator is intended for use by trained medical personnel in outdoor and indoor emergency care settings within the environmental conditions specified. The LIFEPAK 15 monitor/defibrillator is designed to be used

SECTION E: 510(K) SUMMARY

during ground transportation except when specified otherwise. Manual mode monitoring and therapy functions are intended for use on adult and pediatric patients.

Automated external defibrillation mode is intended for use on patients eight years of age and older.

Indications for Use:

Manual Defibrillation:

Indications
Manual defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

Contraindications
Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

Automated External Defibrillation:

Indications
AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 15 monitor/defibrillator is not intended for use on pediatric patients less than 8 years old.

Noninvasive Pacing

Indications
Noninvasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

Contraindications: Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

12-lead Electrocardiography:

Indications

SECTION E: 510(K) SUMMARY

The 12-lead electrocardiogram is used to identify, diagnose and treat patients with cardiac disorders and is useful in the early detection and prompt treatment of patients with acute ST-elevation myocardial infarction (STEMI).

Pulse Oximetry

Indications
Pulse Oximetry is indicated for use in any patient who is at risk of developing hypoxemia, carboxyhemoglobinemia, or methemoglobinemia. SpO_2 monitoring may be used during no motion and motion conditions, and in patients who are well or poorly perfused. SpCO and SpMet accuracies have not been validated under motion or low perfusion conditions.

Noninvasive Blood Pressure Monitoring:

Indications
Noninvasive blood pressure monitoring is intended for detection of hypertension or hypotension and monitoring BP trends in patient conditions such as, but not limited to, shock, acute dysrhythmia, or major fluid imbalance.

End-Tidal CO2 monitoring:

Indications
$EtCO_2$ monitoring is used to detect trends in the level of expired CO_2. It is used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully.

Invasive Pressure Monitoring:

Indications
Invasive pressure monitoring is indicated for use in patients who require continuous monitoring of physiological pressures in order to rapidly assess changes in the patient's condition or response to therapy. It may also be used to aid in medical diagnosis.

Temperature Monitoring:

Indications
Temperature monitoring is indicated for use in patients who require continuous monitoring of body temperature.

SECTION E: 510(K) SUMMARY

Technological characteristics of the proposed and predicate device:

The main difference between the previously cleared predicate LIFEPAK 15 monitor/defibrillator and the proposed LIFEPAK 15 monitor/defibrillator is a combination of software and hardware modifications completed to support component obsolescence. There are no changes to the Shock Advisory System™ algorithm, defibrillation waveform, pacing waveform, indications for use, or monitoring features of the device.

Performance Testing

Performance testing has been completed to demonstrate that the proposed LIFEPAK 15 monitor/defibrillator meets the safety and performance requirements established in the design specifications. Comprehensive verification testing included the following:

- Design Requirements Testing
- Hardware Verification
- Software Performance
- Electrical Safety and Electromagnetic Compatibility
- Design Validation via Animal Studies and Simulated Use Testing

No human clinical studies were submitted as part of this 510(k) Premarket Notification.

Conclusion of Testing

The information in this 510(k) Premarket Notification demonstrates that the proposed LIFEPAK 15 monitor/defibrillator is substantially equivalent to the previously cleared predicate LIFEPAK 15 device with respect to safety, effectiveness, and performance.